

NOV 22 2005

K052977

Premarket Notification 510(k) Summary
As required by section 807.92
Datex-Ohmeda S/5™ Cardiac Output and SvO2 Module, E-COPsv and accessories

GENERAL COMPANY INFORMATION as required by 807.92(a)(1)

COMPANY NAME/ADDRESS/PHONE/FAX:

GE Healthcare
86 Pilgrim Road
Needham, MA 02492 USA
Tel: 781-449-8685
Fax: 781-433-1344

NAME OF CONTACT:

Mr. Joel Kent

DATE:

October 13, 2005

DEVICE NAME as required by 807.92(a)(2)

TRADE NAME:

Datex-Ohmeda S/5™ Cardiac Output and SvO2 Module, E-COPsv and accessories

COMMON NAME:

Cardiac Output, Invasive Pressure, and SvO2 Module

CLASSIFICATION NAME:

The following Class II classifications appear applicable:

<u>Product Code</u>	<u>Classification Name</u>	<u>CFR Section</u>
DQK	Diagnostic, programmable computer	870.1425
DSK	Blood pressure computer	870.1110

NAME OF LEGALLY MARKETED DEVICE FOR WHICH A CLAIM OF SUBSTANTIAL EQUIVALENCE IS MADE as required by 807.92(a)(3)

The Datex-Ohmeda S/5™ Cardiac Output and SvO2 Module, E-COPsv and accessories is substantially equivalent in safety and effectiveness to the legally marketed (predicate) Datex-Ohmeda M COPSv Module (K961063).

DEVICE DESCRIPTION as required by 807.92(a)(4)

E-COPSV is a single-width plug-in parameter module for a Datex-Ohmeda S/5 modular monitoring system. E-COPSV is used for monitoring cardiac output (C.O.), right ventricular ejection fraction (REF) and mixed venous oxygen saturation (SvO2) of hospitalized patients. Invasive pressure measurement is also available. All measurements are invasive.

The E-COPSV module can be used in any of the four Datex-Ohmeda modular monitoring systems with 510(k) clearances: Anesthesia Monitor AM, Compact Anesthesia Monitor CAM, Critical Care Monitor CCM, or Compact Critical Care Monitor CCCM. The Cardiac Output, SvO2 or invasive pressure signal can be displayed on the monitor screen. The waveform size, color and sweep speed can be adjusted. The E-COPSV module calculate a number of parameters related to oxygenation or hemodynamics. All the calculated parameters can be selected on the display, and trended. The Cardiac Output and SvO2 accessories are the same for the E-COPSV module and the predicate device, the M- COPSv (K961063). Accessories that are in contact with the patient are CE-marked by Baxter and distributed by GE Healthcare.

INTENDED USE as required by 807.92(a)(5)Intended Use:

The Datex-Ohmeda S/5™ Cardiac Output and SvO2 module , E-COPSV and accessories is intended for use with Datex-Ohmeda modular monitors for cardiac output (C.O.), right ventricular ejection fraction (REF), mixed venous oxygen saturation (SvO2), and invasive blood pressure monitoring of hospitalized patients..

Indications for use:

The Datex-Ohmeda S/5™ Cardiac Output and SvO2 module, E-COPSV and accessories is used for monitoring cardiac output (C.O.), right ventricular ejection fraction (REF), mixed venous oxygen saturation (SvO2), and invasive blood pressure of hospitalized patients.

The device is indicated for use by qualified medical personnel only.

SUMMARY OF TECHNOLOGICAL CHARACTERITICS OF DEVICE COMPARED TO THE PREDICATE DEVICE as required by 807.92(a)(6)

The Datex-Ohmeda S/5™ Cardiac Output and SvO2 Module, E-COPSV and accessories is substantially equivalent in safety and effectiveness to the legally marketed (predicate) Datex-Ohmeda M COPSv Module (K961063).

The E-COPSV module has the following similarities compared to the predicate M-COPSv (K961063):

- identical intended use and essentially same indications for use (minor text changes for consistency with all other S/5 modules and specifically added invasive blood pressure which was in the predicate device but inadvertently not mentioned in indications statement)
- identical fundamental scientific technology
- same electronic measurement board
- same module software (minor modification and version change)
- same monitor software related to Cardiac Output and SvO2
- use the same operating principle
- same accessories for Cardiac Output and SvO2
- have the same user interface at the monitor and alarms (can be used with the same monitor software)
- the parameter specifications are the same
- have the same safety and effectiveness
- are manufactured using the same processes

The main differences between the new E-COPSV and the predicate M- COPSv (K961063) is primarily due to fact that the new E-COPSV module has the following changes:

- new color, shape, and size and thus differing mechanics
- The front panel and labeling have changed (new GE-type connector for invasive blood pressure)
- New layout of electronic input board between module connector and measurement board
- New layout of electronic measurement board
- Minor software modification
- New invasive blood pressure accessories for the new GE-type connector

Based on the analysis and other documentation included in this 510(k) notification and attachments it is evident that the main features and indications for use of the Datex-Ohmeda S/5™ Cardiac Output and SvO2 Module, E-COPSV are substantially equivalent to the predicate Datex-Ohmeda M-COPSV Module (K961063).

SUMMARY OF NONCLINICAL TESTING FOR THE DEVICE and CONCLUSIONS as required by 807.92(b)(1)(3)

The Datex-Ohmeda S/5™ Cardiac Output and SvO2 Module, E-COPSV and accessories has been assessed against the standards below. The device has been thoroughly tested through validation and verification of specifications.

- COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices
- FDA/DCRND Reviewer Guidance for Premarket Notification Submissions, November 1993
- IEC 60601-1:1988 + Amdt. 1:1991 + Amdt. 2:1995 (Part 1: General requirements for safety)
- EN 60601-1:1990+ A1:1993 + A13:1996 + A2:1995 (identical to IEC60601-1:1988 + Amdt. 1:1991 + Amdt. 2:1995)
- CAN/CSA C22.2 No. 601.1-M90 + S1:1994 (Canadian deviations to IEC 60601-1:1988 + Amdt. 1:1991) + S2:1998 (=IEC Amdt 2:1995)
- UL 2601-1, October 24, 1997 (U.S. deviations to IEC 60601-1:1988 + Amdt. 1:1991+ Amdt. 2:1995)
- IEC 60601-1-2:2001 (Electromagnetic compatibility – Requirements and tests)
- AAMI ES1-1993 (Safe current limits for electromedical apparatus)
- FDA/ODE Guidance for Content of Premarket Submission for Software Contained in Medical Devices. (May 11, 2005)
- ISO 14971:2000, Application of risk management to medical devices
- IEC 60601-2-34 Medical electrical equipment. Part 2: Particular requirements for the safety of Direct Blood Pressure Monitoring Equipment: 2000.
- IEC 60601-2-49 Medical electrical equipment. Part 2: Particular requirements for the safety of MultifunctionPatient Monitoring Equipment: 2001.

CONCLUSION:

The summary above shows that there are no new questions of safety and effectiveness for the Datex-Ohmeda S/5™ Cardiac Output and SvO2 Module, E-COPSV compared to the legally marketed (predicate) Datex-Ohmeda M COPSv Module (K961063).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 22 2005

GE Healthcare
c/o Mr. Joel Kent
Manager, Quality and Regulatory Affairs
86 Pilgrim Road
Needham, MA 02492

Re: K052977

Trade Name: Datex-Ohmeda S/5 Cardiac Output and SvO2 Module, E-COPsv and
Accessories

Regulation Number: 21 CFR 870.1425

Regulation Name: Computer, Diagnostic, Programmable

Regulatory Class: II (two)

Product Code: DQK

Dated: October 17, 2005

Received: October 24, 2005

Dear Mr. Kent:

:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

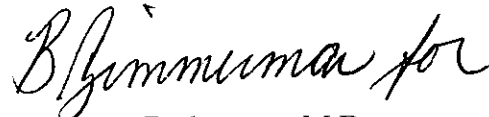
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "B. Zuckerman for".

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052977

Device Name: The Datex-Ohmeda S/5™ Cardiac Output and SvO2 module, E-COPsv and accessories.

Indications for use:

The Datex-Ohmeda S/5™ Cardiac Output and SvO2 module, E-COPsv and accessories is used for monitoring cardiac output (C.O.), right ventricular ejection fraction (REF), mixed venous oxygen saturation (SvO2), and invasive blood pressure monitoring of hospitalized patients.

The device is indicated for use by qualified medical personnel only.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page __ of __

B. Brimmer
Sign-Off
of Cardiovascular Devices
Number K052977